

WHO Information Notice for IVD Users 2020/05

Nucleic acid testing (NAT) technologies that use polymerase chain reaction (PCR) for detection of SARS-CoV-2

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Product type: Nucleic acid testing (NAT) technologies that use polymerase chain reaction (PCR) for detection of SARS-CoV-2

Date: 13 January 2021

WHO-identifier: 2020/5, version 2

Target audience: laboratory professionals and users of IVDs.

Purpose of this notice: clarify information previously provided by WHO. This notice supersedes WHO Information Notice for In Vitro Diagnostic Medical Device (IVD) Users 2020/05 version 1, issued 14 December 2020.

Description of the problem: WHO requests users to follow the instructions for use (IFU) when interpreting results for specimens tested using PCR methodology.

Users of IVDs must read and follow the IFU carefully to determine if manual adjustment of the PCR positivity threshold is recommended by the manufacturer.

WHO guidance Diagnostic testing for SARS-CoV-2 states that careful interpretation of weak positive results is needed (*1*). The cycle threshold (Ct) needed to detect virus is inversely

proportional to the patient's viral load. Where test results do not correspond with the clinical presentation, a new specimen should be taken and retested using the same or different NAT technology.

WHO reminds IVD users that disease prevalence alters the predictive value of test results; as disease prevalence decreases, the risk of false positive increases (*2*). This means that the probability that a person who has a positive result (SARS-CoV-2 detected) is truly infected with SARS-CoV-2 decreases as prevalence decreases, irrespective of the claimed specificity.

Most PCR assays are indicated as an aid for diagnosis, therefore, health care providers must consider any result in combination with timing of sampling, specimen type, assay specifics, clinical observations, patient history, confirmed status of any contacts, and epidemiological information.

Actions to be taken by IVD users:

1. **Please read carefully the IFU in its entirety.**
2. **Contact your local representative if there is any aspect of the IFU that is unclear to you.**
3. **Check the IFU for each incoming consignment to detect any changes to the IFU.**
4. **Provide the Ct value in the report to the requesting health care provider.**

Contact person for further information:

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References:

1. Diagnostic testing for SARS-CoV-2. Geneva: World Health Organization; 2020, WHO reference number WHO/2019-nCoV/laboratory/2020.6.

2. Altman DG, Bland JM. Diagnostic tests 2: Predictive values. BMJ. 1994 Jul 9;309(6947):102. doi: 10.1136/bmj.309.6947.102.